

PCBs & TSCA:

What are PCBs and how are they regulated under TSCA?

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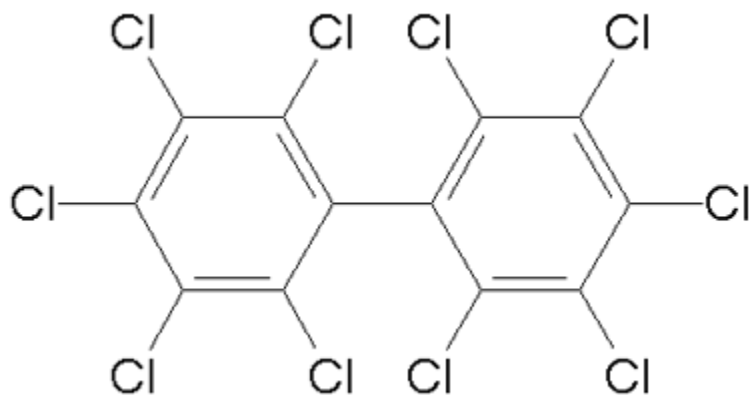


Part I: PCB Chemistry, Uses and Effects

Chemistry of PCBs

- PCBs are a group of 209 similar chemicals
 - individually called congeners
- All are chlorinated aromatic hydrocarbons with the same biphenyl framework structure
- But they have 10 different molecular weights, 10 different levels of chlorination, and 209 different positions of substitution
- PCBs are comparatively stable and unreactive
 - were valued for their excellent fire resistant and dielectric properties
- EPA regulates monochlorinated and dichlorinated biphenyls as PCBs

Chemistry of PCBs



PCB Homolog	Cl Substituents	Number of Congeners
(Biphenyl)	0	(1)
Monochlorobiphenyl	1	3
Dichlorobiphenyl	2	12
Trichlorobiphenyl	3	24
Tetrachlorobiphenyl	4	42
Pentachlorobiphenyl	5	46
Hexachlorobiphenyl	6	42
Heptachlorobiphenyl	7	24
Octachlorobiphenyl	8	12
Nonachlorobiphenyl	9	3
Decachlorobiphenyl	10	1

The Chemistry of Commercial PCBs

- Commercial PCBs were referred to as Aroclors, a trademark used by the major US and world producer Monsanto.
- Aroclors were technical grade mixtures containing as many as 100 different congeners in as many as 6 levels of chlorination.
- The PCB Aroclors were named as 12XX, where XX was the %Chlorine in the Aroclor (exception: Aroclor 1016).
- Synonyms and Trade Names:

Aroclor	Chlorextol	Chlorphen	Clophen	Fenclor
Inerteen	Kanechlor	Phenoclor	Pyralene	Pyranol
Pyrochlor	Santotherm	Sovol	Sovtol	Askarel

The Chemistry of Commercial PCBs

		Percentage of Congeners with Indicated									
		Number of Chlorine Atoms									
Commercial	Percent	1	2	3	4	5	6	7	8	9	10
		Number of Isomers Possible									
PCB Product	Chlorine	3	12	24	42	46	42	24	12	3	1
Aroclor 1232	32	26	29	24	14						
Aroclor 1016	41	2	19	57	22						
Aroclor 1242	42	3	13	28	30	22	4				
Aroclor 1248	48		2	18	40	36	4				
Aroclor 1254	54				11	49	34	6			
Aroclor 1260	60					12	38	41	8	1	

Primary PCB use was as a dielectric fluid in electrical equipment

- Transformers
 - Including railroad transformers
- Capacitors
- Voltage Regulators
- Electromagnets
- Circuit Breakers
- Switches
- Etc.

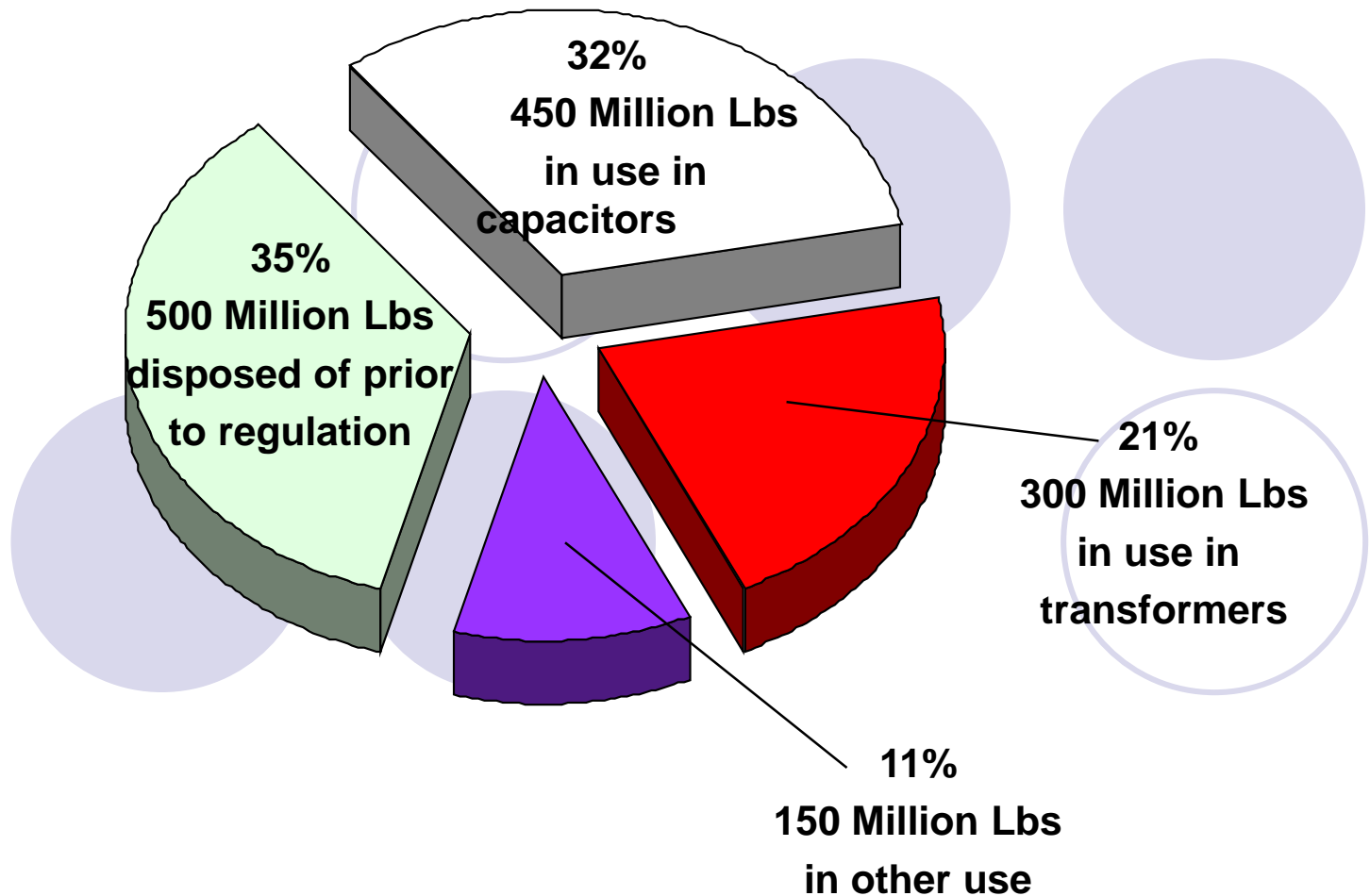


Other PCBs uses

- Hydraulic fluid
- Heat transfer fluid
- Casting waxes
- Lubricating oils
 - In motors, pumps, compressors
- Cutting oils
- Construction materials
 - Caulk, coatings, paints, galbestos
- Shipboard applications
 - Cable, gaskets, insulation, coatings, paint
- Carbonless copy paper
- Scientific instruments & slides



U.S. PCB Status in 1975 (pre-TSCA)



1930-1975 U.S. PRODUCTION TOTAL: 1.4 Billion Pounds (est.)
(About half of total world production)

DRAFT

PCB Health Effects

○ Acute effects (at high doses/exposures; not likely in the general population):

- Chloracne
- Irritation of eyes, face & skin

○ Chronic effects:

Liver Disorders

Potential Developmental Effects (Demonstrated In Animals)

- Reduced birth weight
- Behavioral effects in infants

Cancer

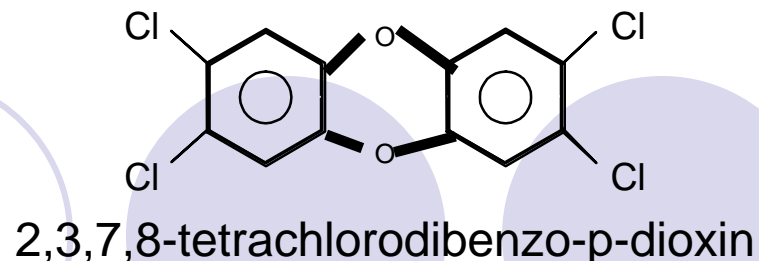
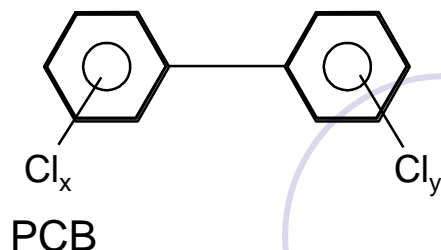
- (Probably) carcinogenic to humans (WHO/IARC change Feb.2013)

Also effects on endocrine, immune and nervous systems

PCB Health Effects

- The majority of studies/research on health effects of PCBs in both humans and animals has been conducted using commercial mixtures (e.g., Aroclors)
 - Studies have also been conducted on individual congeners to understand the relative contribution and potency of individual congeners to the health effects observed from exposure to commercial mixtures
- When commercial mixtures are released to the environment, the differing properties of individual congeners influence their environmental fate such that environmental exposures may be to different congeners or mixtures than the original commercial mixture
 - Congener-specific understanding of health effects allow us to better assess “environmental” mixtures that vary from commercial mixtures

PCB Health Effects: Dioxin-Like Toxicity



□ Chemical structural similarity

- Only 12 of 209 PCB congeners exhibit dioxin-like toxicity
 - higher chlorinated congeners: 2 tetra/5 penta/4 hexa/1 hepta
 - Toxicity Equivalence ranging from 0.1 to 0.00003 as toxic as Dioxin
- Many of the well established health effects associated with commercial PCB mixtures have been causally linked to the dioxin-like congeners

- ## □ However, study of individual congeners – both dioxin-like and non-dioxin-like – is making clearer which individual PCB congeners can cause which of the health effects associated with PCBs



Part II: TSCA PCB Regulations

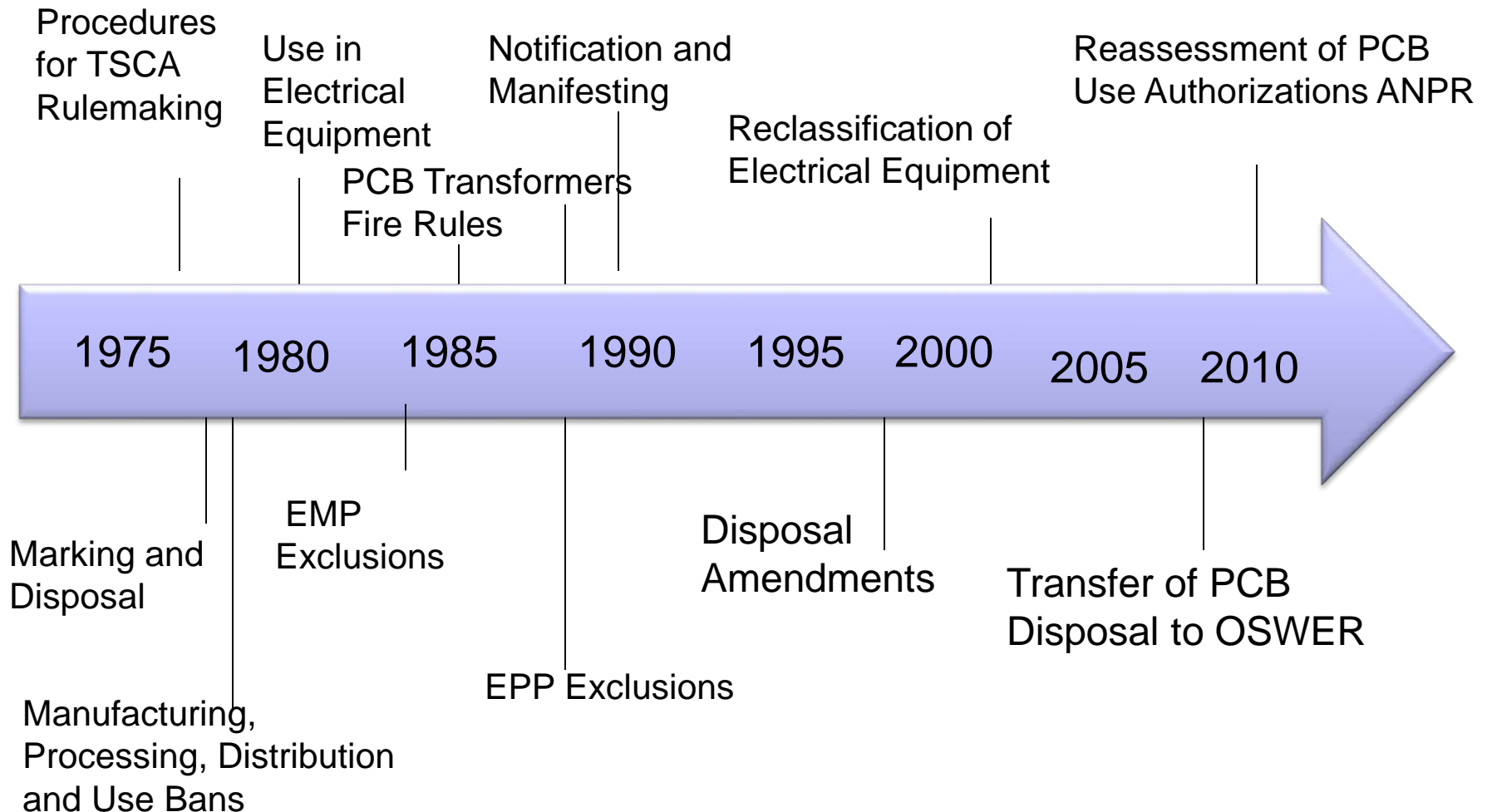
Toxic Substances Control Act

Section 6(e)

- PCB-specific amendment to the 1976 Act
- Controls all aspects of the PCB life-cycle:
 - Manufacturing (import)
 - Processing
 - Distribution-in-commerce (export)
 - Use
 - Marking
 - Disposal
- Implementing regulations at 40 CFR Part 761
 - Over 100 pages of final regulations
- Numerous rules promulgated since 1978
 - Last major revisions in 1998

History of PCB Regulations

Chronological Overview



Major PCB Regulations

- PCBs; Marking and Disposal (1978)
- PCBs, Manufacturing, Processing, Distribution in Commerce and Use Bans (1979)
- PCBs in Electrical Equipment Rule (1982)
- Manufacturing, Processing, Distribution & Use Prohibitions (1984)
 - Established regulations for inadvertently generated PCBs below 50 ppm
- PCBs in Electrical Transformers (Fire Rules) (1985 & 1988)
- Exclusions, Exemptions and Use Authorizations (1988)
 - Addressed legacy PCB uses < 50 ppm not covered by 1984 rule
- Notification and Manifesting for PCB Waste Activities (1989)
- Disposal of Polychlorinated Biphenyls (1998)
- Reclassification of PCB & PCB-Contaminated Electrical Equipment (2001)
- Advanced Notice of Proposed Rulemaking: Reassessment of PCB Use Authorizations (2010)

TSCA PCB Regulations:

40 CFR Part 761 in Summary:

- Bans manufacturing and processing, unless exempted by rule
 - Standing exemptions for R&D and scientific uses
 - Petition process available (but very cumbersome)
- Bans distribution, unless totally enclosed or authorized PCBs
 - Intact, non-leaking electrical equipment (deemed “totally enclosed”)
 - PCB waste for disposal
- Bans use/storage, unless authorized by rule
 - Certain electrical equipment and other uses ≥ 50 ppm (e.g., carbonless copy paper; research and development; natural gas pipelines; porous surfaces contaminated by spills; decontaminated materials)
- Disposal – Regulates disposal of PCBs ≥ 50 ppm
 - Remediation (cleanup) wastes may be subject < 50 ppm
- Certain broad exclusions for < 50 ppm PCBs

Exclusions for <50 ppm PCBs: History

- EPA established a 50 ppm cutoff in 1979 based on consideration of costs and benefits:
 - Economic impact
 - Technological impact on organic chemicals industry
 - Avoid regulation of ambient levels of PCBs in air or water thru TSCA
 - Effective implementation
 - Regulating diffuse and extremely numerous sources below 50 was impractical
 - PCB disposal capacity and agency enforcement resources would be overtaxed by low level materials, leading to improper management of high concentration waste
- In 1980 Court of Appeals (DC) overturned this cutoff, leading to new EPA regulations for < 50 PCBs
 - EPA re-examined risks and benefits of uses below 50 ppm in detail to substantiate new rules for these uses

Exclusions for <50 ppm PCBs: Overview

- General exclusions of some <50 ppm PCBs (761.20); promulgated via rulemaking (at least 5 rules), each with public notice-and-comment opportunity:
 - excluded manufacturing processes (EMP): ongoing inadvertent generation
 - excluded PCB products (EPP): historical (pre 10/1/84) contamination
 - recycled PCBs: paper and asphalt roofing shingles only
- Manufacturing/import: EMPs
- Processing and distribution in commerce: products of EMPs, EPPs and recycled PCBs.
- Use: products of EMPs, EPPs, recycled PCBs, and sewage sludge

Excluded Manufacturing Process Rule (Inadvertently Generated PCBs)

- 1984 Final Rule (July 10, 1984: 49 FR 28172)
 - Result of EDF court case/consensus proposal
- 200 chemical processes reviewed
 - 70 high probability of producing PCBs
 - Chlorinated pigments/dyes included
- Pigment & dye, paint, paper and printing companies participated
- 100,000 lbs./year inadvertent generation of PCBs, of which:
 - 11,000 lbs./year in products (including chemical intermediates)
 - 1000 lbs./year released to the environment
 - [Versus 180 million lbs. released to environment pre-TSCA]

EMP Conditions

- Inadvertently generated PCBs
- Annual average <25 ppm; 50 ppm maximum concentration
 - Lower limit of 5 ppm set for detergent bars
 - Discounting factor for monochlorinated (50x) and dichlorinated biphenyls (5x) because they are less persistent in the environment and less likely to bioaccumulate
- Controls on manufacturing waste/releases
 - Air emissions less than 10 ppm
 - Water discharges less than 100 micrograms per liter
 - Disposal of any process wastes \geq 50 ppm regulated as PCB waste
- Reporting and Recordkeeping Requirements

EMP Notices

- Notify EPA if manufacturing/importing products with > 2 ppm PCB concentration (in any resolvable gas chromatographic peak)
 - Approximately 80 notices from 28 companies on file
 - Records only since 1994: maintained in EPA docket
- Must file within 90 days, including basic information (number, type, location of processes) and certification
 - Information may be claimed as proprietary (CBI)
 - Supporting records must be maintained for 3 years
- Notice also required if air/water releases exceed 10 lbs/year

Part III: EPA's Reassessment of PCB Use Authorizations



EPA's Reassessment of PCB Use Authorizations

- Millions of pounds of contaminated liquid estimated to remain in authorized use in equipment (primarily electrical)
 - Including at very high concentrations (e.g., 500,000 ppm or greater)
 - Are well known to include “dioxin-like” congeners
 - Age (30+ years) and condition of this equipment a concern
 - Decreasing economic importance a factor
- Emerging issues with non-liquid PCBs (e.g., caulk and paint) in use
 - Also at very high concentrations (e.g., caulk up to 30% PCBs = 300,000 ppm)
 - Are well known to include “dioxin-like” congeners

EPA's 2010 Advance Notice on Reassessment of PCB Use Authorizations

- EPA solicited comments and data needed to characterize/understand ongoing sources and releases of PCBs:
 - Liquid PCBs in equipment and pipelines
 - Elimination of most use authorizations at levels ≥ 50 ppm
 - Non-liquid PCBs (including caulk)
 - Porous surfaces with PCBs
 - Definitional and marking issues
 - Use of 50 ppm level for excluded products/processes
 - Lowering the Level of Quantitation (LOQ) from 2 to 1 ppm

Comments on the ANPR

- 242 comments in docket; about 148 individual commenters
- Major groups of commenters
 - Electrical utilities (industry)
 - Natural gas transmitters and distributors (e.g., INGAA, AGA)
 - Parents and workers in New York City schools (caulk)
 - Metal/plastic recyclers (e.g., ISRI, MBA Polymers)
 - Governments (DOE, Mass. DEP, Wash. DEP, Tribes, local)
 - Recycled paper producers (Inland Paper)
 - Pigment manufacturers (Color & Pigment Manufacturers Ass'n)

Excluded Manufacturing Process/Products: Comments

- Washington State Department of Ecology
 - Significant amounts of PCBs flow into Puget Sound; primary source is runoff; “. . . do not have estimate for which sources of PCBs are contributing most to loading”
 - Does not “recommend that the EPA authorize the use of caulk, paint, or other non-liquid PCB product at concentrations exceeding the level of 50 ppm currently provided . . . for excluded PCB products”
- California Regional Water Quality Board
 - “In development of this TMDL, we learned that PCBs releases from uncontained spills and outdated products are the largest ongoing sources of PCBs in our waterways” (e.g., caulk, paint, other building materials)
 - Consider water quality impacts when reducing the exclusion concentration for PCBs
- Confederated Tribes of the Umatilla Indian Reservations (CTUIR)
 - “CTUIR DNR supports the elimination of PCBs from all dyes, pigments and inks”
 - Overseas manufacturers send products to U.S. and U.S. companies must clean up contamination to meet water quality standards

Excluded Manufacturing Process/Products: Comments

- Inland Paper/Spokane Riverkeeper/The Lands Council
 - Eliminate all federal exclusions or exceptions for inadvertently formed PCBs as a byproduct or impurity in chemical manufacturing processes
 - Monochloro-biphenyls and Dichloro-biphenyls should be excluded from total PCB regulation due to lower potential for bioaccumulation and human health toxicity
- Northwest Pulp and Paper Association (NWPPA)
 - NWPPA supports lowering the allowable concentration of PCBs in dyes, inks and pigments products as much as possible, using a phased approach, as the best mechanism for reducing PCB contamination in recycled furnish
 - Such action must be coordinated and connected federal and state actions involved in developing water quality criteria and implementation
- American Forest and Paper Association (AF&PA)
 - Carbonless copy paper manufactured in the U.S. no longer contains PCBs; AF&PA encourages EPA to discontinue use authorization for PCBs in manufactured/imported carbonless copy paper
 - PCBs in azo and phthalocyanine pigments should be banned from U.S. commerce, including imported products and packaging

Excluded Manufacturing Process/Products: Comments

- Color Pigment Manufacturers Association (CPMA)
 - 1 ppm threshold would eliminate three important pigment groups from commerce, affecting color printing as well as colors in paint and plastics
 - Technology does not now exist to eliminate PCBs in all organic pigments to a level below 1 ppm
 - Would put U.S. pigment and product manufacturers at additional competitive disadvantage versus pigment and product importers
- Representative Mike Simpson (Idaho) letter to EPA (outside ANPRM process)
 - “EPA regulations inequitably allow overseas manufacturers to export PCB containing products into the U.S. with concentrations up to 50 ppm, while then subjecting our own businesses and communities to surface water quality standards that are nearly 8 million times more stringent”
 - “Manufacturing alternatives for similar dyes and pigments that do not contain PCBs are available”

Proposed Rule Under Development

- Scope of proposal
 - Remove use provisions no longer necessary (e.g., use authorizations for equipment that is no longer being used)
 - Incorporate regulatory fixes where decades of experience shows provisions need updating
- Changing need for uses after 35 years
 - Cost of disposal is lower
 - Equipment is older and more prone to failure
 - Substitutes available
- Focusing on major remaining reservoirs of liquid dioxin-like PCBs, primarily in electrical equipment such as electrical transformers and capacitors in fluorescent light ballasts.
- EPA believes this effort will produce the greatest reduction in potential exposure from spills and catastrophic events and contribution to ongoing and future contamination of the environment by dioxin-like PCB uses
- Intend to publish proposed rule in early 2015

Part IV: Considering Inadvertently Generated PCBs



Challenges



- Under TSCA, regulatory changes require notice-and-comment rulemaking, which presents significant legal, analytical, procedural and resource challenges for EPA
- EPA must consider economic impacts under TSCA section 6; benefits (risk reduction) must be weighed against the costs of a regulation
- EPA previously determined mono and dichloro PCBs are less persistent and less likely to bioaccumulate while the cost to prevent generation would be high (rationale for “discounting” factors)
- Inadvertently generated PCBs (e.g., PCB-11 or PCB 209) are not “dioxin-like” PCBs nor generally part of Aroclor mixtures, so much less studied
- Based on limited data and knowledge of properties, many are expected to behave differently from dioxin-like congeners in biological systems and the environment, therefore, would need their own congener- or process-specific risk assessment(s).
- At present, there are not sufficient data to assess the risks of these inadvertently generated PCBs

EPA Actions

- As a start, EPA has requested that toxicity testing on PCB-11 be conducted through the National Toxicology Program at the National Institute of Environmental Health Sciences
 - Existing data on PCB-11 presence in the environment makes this particular inadvertently-generated congener a good candidate for toxicity testing
- EPA is also examining the characterization of PCBs in water bodies
 - Aggregation of all PCBs in water quality criteria (i.e., expressed as total PCBs) in some instances may be problematic for risk assessments
 - A single water quality number for PCBs may not adequately represent the variable toxicity of the congeners actually present
- EPA is interested in pursuing voluntary approaches, such as P2 and green chemistry, to get results sooner than can be achieved through regulation.